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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,572	10/31/2003	Nicholas P. Barker	50206/012002	1119

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CLARK & ELBING LLP
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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
08/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/698,572	BARKER ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,2 and 7-22* is/are pending in the application.

4a) Of the above claim(s) *8-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2, 7 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-2008; 12-2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The responses filed 12-19-07 and 5-7-08 and the amendments filed 12-19-07 and 5-7-08 have been entered into the record. Claims 3-6 and 23-42 have been cancelled. Claims 1, 2 and 7-22 are pending. Claims 1, 2, 7, and 20-22 are under examination. Claims 8-19 are withdrawn from consideration as drawn to non-elected species.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 8-19 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The objection under 37 CFR 1.78(b) is withdrawn based on Applicants amendment to the claims.

The rejection of claims 1-4, 6, 7 and 20-22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the amendment to the claims.

The rejection of claims 1, 6, 7 and 22 under 35 U.S.C. 102(b) as being anticipated by Podolsky et al (US Patent No. 6,063,755 issued May 16, 2000; of record) is withdrawn based on Applicants amendments to the claims.

Rejections Maintained

Claims 1, 7 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-17 of U.S. Patent No.6,221,840 is maintained for reasons made of record and held in abeyance.

Claims 1, 6, 7 and 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.6,525,018 is maintained for reasons made of record and held in abeyance.

Claims 1, 6, 7 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No.6,063,755 is maintained for reasons made of record and held in abeyance.

Claims 1-4, 6-7, and 20-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the specifically indicated claims of copending Application Nos. 10/235,238 (claims 1 and 6-13); 10/266,069 (Claims 1-27); 10/305,747 (claims 1-5 and 7-33), 10/313,642 (claims 1, 3-7 and 10-21), 10/353,334 (claims 7-18), 10/397,953 (claims 12-15, 17, 23-25 and 27-35); 10/431,805 (claims 1-23); 10/434,607 (claims 1-22 and 38-58); 10/434,636 (claims 1-21); 10/434,752 (claims 1-4, 6, 11-21 and 41-51); 10/435,406 (claims 1-21 and 38-51); 10/449,456 (claims 1-6, 9, 10, 13 and 14); and 10/457,157 (claims 1-21), 11/275,599 (claims 2-10) is maintained for reasons made of record and held in abeyance.

Claims 1, 2, 7 and 20-22 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons made of record in the Office Action mailed 6-15-07 and herein.

Applicant's arguments have been carefully considered but are not persuasive. Applicant's arguments have been carefully considered but are still not persuasive.

Applicants argue that practicing the claims is straightforward and are fully enabled as of the earliest priority document. This is not persuasive, the specification and the earliest priority document are not enabled for the claims. The following facts are noted. The claims require that administration ***prevent or treat*** and the specification does not teach that either intact human intestinal trefoil factor (hITF) or specifically claimed fragments thereof are effective to treat or prevent epithelial lesions in general or specifically the elected species. No evidence is prevented that trefoil peptides can prevent lesions such as abrasions, surgical wounds or traumatic wounds as encompassed by the claim or other epithelial lesions exemplified in the previous office action. Furthermore, no evidence is prevented that the trefoil peptides prevent or treat epithelial lesions such as viral lesions (herpes chancre sores, chicken pox, rubella) or bacterial lesions such as acne. The trefoil peptides have not been demonstrated to have either anti-bacterial or anti-viral activity and therefore, one skilled in the art would have reason to doubt its efficacy for such. It is not evident that any epithelial lesion can be treated or prevented. The art of record characterizes it as a mucosal associated factor and has wound healing activity at mucosal surfaces. The skin is not a mucosal surface. Applicants argue that there is no requirement that all embodiments be operative and that the office has not provided evidence or reasons to doubt the enablement of the claimed invention and that the references are not on point and that the 22 references cited in the action do not provide reasons to doubt the specification. This is not persuasive because the references collectively cast doubt on the enablement of both intact hITF and the claimed fragments for the breadth of the now claimed invention. Many of the reference establish the state of the art at the time of filing and also address trefoil factors in particular and lack of success with mucosal epithelial wound healing, the controversial results in the art and the unpredictability of routes of administration. This is also not persuasive because in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)

(contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright,* 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck,* 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). The specification and the art lacks in vitro data that has a predictable correlation with in vivo results directed to the claimed fragments. It is not evident from Applicants disclosure that epithelial lesions, as broadly defined in the art, can be either treated or prevented as broadly claimed or commensurate with the elected specie. Applicants argue that each claim should be addressed individually. All claims have been addressed appropriately. Applicants are simply not enabled for use of any fragment for treating or prevention epithelial lesions, administered by any route as set forth in the claims.

The rejection is maintained.

Claims 1, 7 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Podolsky, (WO 97/38712, published 23 October 1997; of record) is maintained for reasons made of record.

Applicants argue that Podolsky does not teach or suggest the claimed fragments. This is not persuasive, the human intestinal trefoil fragments are taught by Podolsky. The fragments (from about the first cysteine residue involved in a disulphide bond of the three loop structure to about the last cysteine residue involved in disulfide bond of the three loop structure; page 8, lines 1-10) variants thereof and members of the trefoil family, can be used in treatment abrasions of the surface of the eye (i.e. cornea, page 36 second full paragraph), no matter how the injury is caused and treatment of the gastrointestinal tract from damage cause by radiation therapy or chemotherapy by promoting the maintenance of mucosal integrity. Podolsky teaches the treatment of lesions inside and outside the alimentary canal (page 10) including ulcers. As such the claimed invention is anticipated by the reference.

Status of Claims

Claims 1, 2, 7 and 20-22 stand rejected. Claims 8-19 are withdrawn from consideration.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on **M**-Th 7:30 am - 6:00 pm. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Shanon Foley can be reached on 571-272-0898 or Robert Mondesi at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645